510(K) SUMMARY K132472

Submitter Information

Submitter's Name: JustRight Surgical LLC
Address: 6235 Gunpark Drive #G
Boulder, CO 80301
Telephone: 720-287-7130
Fax: 720-287-7130

Contact Person: Michele Lucey
Telephone: 603-748-1374

FEB 11 2014

Date Prepared: December 12, 2013

Device Trade Name: JustRight™ 5mm Stapler System

Classification: Class II

Product Code(s): GDW, GAG

Common and Usual Name: Implantable Staple

Classification Name: Implantable Staple

Regulation Number(s): 878.4750

Predicate Devices: Covidien Endo GIA™ 30mm 2.0 Size Staple, K892233, K900129, K061095,

Intended Use:
The JustRight™ 5mm Stapler is intended for use in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis.

Device Description/Technological Characteristics:
The JustRight™ 5mm Stapler places two 25mm staggered rows of titanium staples while simultaneously dividing the tissue between the two staple rows. The unformed staple size is 2mm from staple backspan to staple leg tip. The system is provided with a stapler handle with one pre-loaded staple cartridge and reload cartridges are provided separately to allow for multiple staple line applications within one surgical procedure. The JustRight™ Stapler is compatible for introduction and use through a 5mm cannula sleeve and the stapler handle has a rotation knob to allow for 360° rotation of the staple cartridge.

Non-Clinical Performance Data:
In vivo and *in vitro* testing of the JustRight ™ 5mm Stapler System was performed to evaluate device function and durability in order to demonstrate that the device is safe and effective and performs as intended. The testing conducted is summarized as follows:

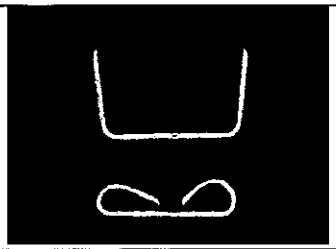
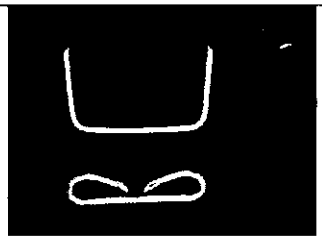
- In vitro Testing
  - Device durability (multiple firings)
  - Staple formation
  - Device actuation and reload performance
- In vivo Testing (includes comparative testing to predicate device to demonstrate substantial equivalence)
  - Tissue trauma evaluation
  - Knife cutting performance
  - Device actuation and reload performance
  - Staple formation
  - Staple line integrity
- Biocompatibilty testing was conducted in accordance with ISO 10993.

The results of these tests demonstrate that the JustRight™ 5mm Stapler System is substantially equivalent to the predicate device.

Substantial Equivalence:

Comparison to predicate device:

Device Feature	JustRight™ 5mm Stapler System	Covidien Endo GIA™	Comments on Differences
Product Code	GDW, GAG	Same	
Regulation Number	878.4750	Same	
Regulation Name	Implantable Staple	Same	
Implantable Staple Material	Titanium (ASTM F67-06)	Same	
Intended Use	Intended for use in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation	Same	

Device Feature	JustRight™ 5mm Stapler System	Covidien Endo GIA™	Comments on Differences
	of anastomosis		
Anatomical Sites	Abdominal and thoracic procedures	Same	
Unformed staple leg length	2mm	Same	
Staple wire diameter	.2mm	Same	
Staple shape	B shaped	B shaped	
Staple Image			
Indicated tissue thickness	.75-1.0mm	Same	
Cartridge length	30mm	50mm	Overall size does not affect function
Staple line length	25mm	30mm	The difference in length limits the flattened length for transection
Number of staples per line	6	8	The difference in length limits the flattened length for transection. The number of staples per mm is the same.
Number of staple lines per cartridge	4	6	Staple line integrity (burst) testing was conducted to compare the JustRight Stapler to the predicate. The results showed equivalence in staple line integrity

Device Feature	JustRight™ 5mm Stapler System	Covidien Endo GIA™	Comments on Differences
Staple line configuration	Staggered	Same	
Operation	Manual	Same	
Integrated knife blade to cut between staple line	Yes	Same	
Staples beyond knife cut	Yes	Same	
Endoscopic use	Yes	Same	
Minimum endoscopic cannula size	5.5mm	12mm	The cannula size is for compatibility and does not affect function
Shaft length	20 cm	6,16, and 26 cm	The shaft length of the JustRight Stapler is within the range offered for the predicate
Shaft Diameter	5mm	12mm	Device performance is not dependent on the shaft diameter. The diameter only means that different sized trocar cannulas are used for insertion.
Shaft rotation	360°	Same	
Cartridge articulation	No	Yes	
Reloadable	Yes	Same	
Reload limits	Up to 15 staple firings per handle	Up to 25 staple firings per handle	The number of staple firings for the JustRight device is reasonable for a single use device and the number of staple

Device Feature	JustRight™ 5mm Stapler System	Covidien Endo GIA™	Comments on Differences
			firings performed within a single surgical procedure.
Safety lock	Yes	Same	
Atraumatic tissue clamp	Yes	Same	
How Supplied	Sterile single use only	Same	
Biocompatibility	Tissue contact materials are biocompatible per ISO 10993	Same	
Sterilization	Ethylene Oxide	Same	
Sterility Assurance Level	10^{-6}	Same	
Endotoxin Limit	20 EU per Product	Same	
Package	Tyvek/Blister Tray	Same	
Labeling	Conforms to 21 CFR Part 801	Same	

The JustRight™ 5mm Stapler System and the predicate device, the Endo Gia™ 30 mm 2.0 Stapler, have the same intended use, similar technological characteristics, identical staple size and material, and similar principals of operation. Where there are differences those have been explained in the table above. These differences do not affect substantial equivalence. The JustRight™ 5mm Stapler System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 11, 2014

JustRight Surgical LLC
Ms. Michele Lucey
Lakeshore Medical Device Consulting, LLC
128 Blye Hill Landing
Newbury, NH 03255

Re: K132472
Trade/Device Name: JustRight 5mm Stapler System
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable staple
Regulatory Class: Class II
Product Code: GDW, GAG
Dated: December 12, 2013
Received: December 26, 2013

Dear Ms. Lucey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause-S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132472

Device Name
JustRight 5mm Stapler System

Indications for Use *(Describe)*

The JustRight 5mm Stapler is intended for use in abdominal, gynecologic, pediatric and thoracic surgery for resection, transection and creation of anastomosis.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Jiyoung Dang -S

PSC Publishing Services (301) 443-6740 EF